

(d) *Admission of liability not required.* A manufacturer reporting to the Commission under section 37 need not admit that the information it reports supports the conclusion that its consumer product caused a death or grievous bodily injury.

§ 1116.7 Scope of section 37 and its relationship to section 15(b) of the CPSA.

(a) According to the legislative history of the Consumer Product Safety Improvement Act of 1990, the purpose of section 37 is to increase the reporting of information to the Commission that will assist it in carrying out its responsibilities.

(b) Section 37(c)(1) requires a manufacturer or importer (hereinafter “manufacturer”) to include in a section 37 report a statement as to whether a civil action that is the subject of the report alleged death or grievous bodily injury. Furthermore, under section 37(c)(2), a manufacturer may specifically deny that the information it submits pursuant to section 37 reasonably supports the conclusion that its consumer product caused a death or grievous bodily injury, and may also include any additional information that it chooses to provide. In view of the foregoing, the reporting obligation is not limited to those cases in which a product has been adjudicated as the cause of death or grievous injury or to those settled or adjudicated cases in which the manufacturer has satisfied itself that the product was the cause of such trauma. Rather, when the specific injury alleged by the plaintiff meets the definition of “grievous bodily injury” contained in § 1116.2(b) of this part, the lawsuit falls within the scope of section 37 after settlement or adjudication. The manufacturer’s opinion as to the validity of the allegation is irrelevant for reporting purposes. The category of injury alleged may be clear from the face of an original or amended complaint in a case or may reasonably be determined during pre-complaint investigation, post-complaint discovery, or informal settlement negotiation. Conclusory language in a complaint that the plaintiff suffered grievous bodily injury without further elaboration raises a presumption that the injury

falls within one of the statutory categories, but is insufficient in itself to bring the suit within the ambit of the statute, unless the defendant manufacturer elects to settle such a matter without any investigation of the underlying facts. A case alleging the occurrence of grievous bodily injury in which a litigated verdict contains express findings that the injury suffered by the plaintiff did not meet the statutory criteria is also not reportable. Should a manufacturer believe that its product is wrongly implicated in an action, the statute expressly incorporates the mechanism for the manufacturer to communicate that belief to the Commission by denying in the report the involvement of the product or that the injury in fact suffered by the plaintiff was not grievous bodily injury, despite the plaintiff’s allegations to the contrary. In addition, the statute imposes stringent confidentiality requirements on the disclosure by the Commission or the Department of Justice of information submitted pursuant to sections 37(c)(1) and 37(c)(2)(A). Moreover, it specifies that the reporting of a civil action shall not constitute an admission of liability under any statute or common law or under the relevant provisions of the Consumer Product Safety Act. In view of these safeguards, the reporting of lawsuits alleging the occurrence of death or grievous injury should have little adverse effect on manufacturers.

(c) Section 37 applies to judgments and “final settlements”. Accordingly, the date on which a civil action is filed or the date on which the product that is the subject of such an action was manufactured is irrelevant to the obligation to report. A settlement is final upon the entry by a court of an order disposing of a civil action with respect to the manufacturer of the product that is the subject of the action, even though the case may continue with respect to other defendants.

(d) A judgment becomes reportable upon the entry of a final order by the trial court disposing of the matter in favor of the plaintiff and from which an appeal lies. Because section 37(c)(2) specifies that a reporting manufacturer

may include a statement that a judgment in favor of a plaintiff is under appeal or is expected to be appealed, Congress clearly intended section 37 to apply prior to the exhaustion of or even the initiation of action to seek appellate remedies.

(e) No language in section 37 limits the reporting obligation to those litigated cases in which the plaintiff prevails completely. Therefore, if a court enters a partial judgment in favor of the plaintiff, the judgment is reportable, unless it is unrelated to the product that is the subject of the suit. For example, if a manufacturer's product is exonerated during a suit, but liability is assessed against another defendant, the manufacturer need not report under section 37.

(f)(1) Section 37 applies to civil actions that allege the involvement of a particular model of a consumer product in death or grievous bodily injury. Section 3(a) of the Consumer Product Safety Act (15 U.S.C. 2052(a)) defines a "consumer product" as any article, or component part thereof, produced or distributed for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or for the personal use, consumption, or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise. The term "consumer product" does not include any article which is not customarily produced or distributed for sale to, or use or consumption by, or enjoyment of, a consumer.

(2) Since section 37 focuses on consumer products, it is the responsibility of the manufacturer of a product implicated in a civil action to determine whether the production or distribution of the product satisfies the statutory criteria of section 3(a). If it does, the action falls within the ambit of section 37. True industrial products are beyond the scope of section 37. However, if a lawsuit is based on an allegation of injury involving a consumer product, that suit falls within the scope of section 37, even though the injury may have occurred during the use of the product in employment. By the same token, occupational injuries arising during the fabrication of a consumer

product are not reportable if the entity involved in the injury is not a consumer product at the time the injury occurs. In determining whether a product meets the statutory definition, manufacturers may wish to consult the relevant case law and the advisory opinions issued by the Commission's Office of the General Counsel. The unique circumstances surrounding litigation involving asbestos-containing products warrant one exception to this analysis. The Commission, as a matter of agency discretion, will require manufacturers of such products to report under section 37 only those lawsuits that allege the occurrence of death or grievous bodily injury as the result of exposure to asbestos from a particular model of a consumer product purchased by a consumer for personal use. Such lawsuits would include not only injury to the purchaser, but also to other consumers including family, subsequent property owners, and visitors. The Commission may consider granting similar relief to manufacturers of other products that present a risk of chronic injury similar to that presented by asbestos. Any such request must contain documented evidence demonstrating that compliance with the reporting requirements will be unduly burdensome and will be unlikely to produce information that will assist the Commission in carrying out its obligations under the statutes it administers.

(g) The definition of "consumer product" also encompasses a variety of products that are subject to regulation under the Federal Hazardous Substances Act (15 U.S.C. 1261 *et seq.*), the Poison Prevention Packaging Act (15 U.S.C. 1471 *et seq.*), the Flammable Fabrics Act (15 U.S.C. 1191 *et seq.*), and the Refrigerator Safety Act (15 U.S.C. 1211 *et seq.*). Lawsuits involving such products are also subject to section 37, notwithstanding the fact that the products may be regulated or subject to regulation under one of the other statutes.

(h) Relationship of Section 37 to Section 15 of the CPSA.

(1) Section 37 plays a complementary role to the reporting requirements of section 15(b) of the CPSA (15 U.S.C.

2064(b)). Section 15(b) establishes a substantial obligation for firms to review information as it becomes available to determine whether an obligation to report exists. Accordingly, the responsibility to report under section 15(b) may arise long before enough lawsuits involving a product are resolved to create the obligation to report under section 37. The enactment of section 15(b)(3) in the Consumer Product Safety Improvement Act of 1990 reinforces this expectation. Under this amendment, manufacturers must report to the Commission when they obtain information that reasonably supports the conclusion that a product creates an unreasonable risk of serious injury or death. Previously, the reporting obligation for unregulated products only arose when available information indicated that the product in question was defective and created a substantial product hazard because of the pattern of the defect, the severity of the risk of injury, the number of products distributed in commerce, etc. The effect of the 1990 amendment is discussed in detail in the Commission's interpretative rule relating to the reporting of substantial product hazards at 16 CFR part 1115.

(2) The new substantive reporting requirements of section 15(b)(3) support the conclusion that Congress intended section 37 to capture product-related accident information that has not been reported under section 15(b). Between the time a firm learns of an incident or problem involving a product that raises safety-related concerns and the time that a lawsuit involving that product is resolved by settlement or adjudication, the firm generally has numerous opportunities to evaluate whether a section 15 report is appropriate. Such evaluation might be appropriate, for example, after an analysis of product returns, the receipt of an insurance investigator's report, a physical examination of the product, the interview or deposition of an injured party or an eyewitness to the event that gave rise to the lawsuit, or even preparation of the firm's responses to plaintiff's discovery requests. Even if a manufacturer does not believe that a report is required prior to the resolution of a single lawsuit, an obligation to inves-

tigate whether a report is appropriate may arise if, for example, a verdict in favor of the plaintiff raises the issue of whether the product in question creates an unreasonable risk of death or serious injury.

(3) In contrast, the application of section 37 does not involve the discretionary judgment and subjective analyses of hazard and causation associated with section 15 reports. Once the statutory criteria of three settled or adjudicated civil actions alleging grievous injury or death in a two year period are met, the obligation to report under section 37 is automatic. For this reason, the Commission regards section 37 as a "safety net" to surface product hazards that remain unreported either intentionally or by inadvertence. The provisions in the law limiting such reports to cases in which three or more lawsuits alleging grievous injury or death are settled or adjudicated in favor of plaintiffs during a two year period provide assurance that the product involved presents a sufficiently grave risk of injury to warrant consideration by the Commission. Indeed, once the obligation to report under section 37 arises, the obligation to file a section 15 report concurrently may exist if the information available to the manufacturer meets the criteria established in section 15(b) for reporting.

(4) Section 37 contains no specific record keeping requirements. However, to track and catalog lawsuits to determine whether they are reportable, prudent manufacturers will develop and maintain information systems to index and retain lawsuit data. In the absence of a prior section 15 report, once such systems are in place, such manufacturers will be in a position to perform a two-fold analysis to determine whether the information contained in such systems is reportable under either section 15(b) or 37. A manufacturer might conclude, for example, that the differences between products that are the subject of different lawsuits make them different models or that the type of injury alleged in one or more of the suits is not grievous bodily injury. Based on this analysis, the manufacturer might also conclude that the suits are thus

Consumer Product Safety Commission

§ 1116.8

not reportable under section 37. However, a reporting obligation under section 15 may exist in any event if the same information reasonably supports the conclusion that the product(s) contain a defect which could create a substantial product hazard or create an unreasonable risk of serious injury or death.

§ 1116.8 Determination of particular model.

(a) The obligation rests with the manufacturer of a product to determine whether a reasonable basis exists to conclude that a product that is the subject of a settled or adjudicated lawsuit is sufficiently different from other similar products to be regarded as a “particular model” under section 37 because it is “distinctive.” To determine whether a product is “distinctive”, the proper inquiry should be directed toward the degree to which a product differs from other comparable products in one or more of the characteristics enumerated in section 37(e)(2) and § 1116.2(c) of this part. A product is “distinctive” if, after an analysis of information relating to one or more of the statutory characteristics, a manufacturer, acting in accordance with the customs and practices of the trade of which it is a member, could reasonably conclude that the difference between that product and other items of the same product class manufactured or imported by the same manufacturer is substantial and material. Information relevant to the determination of whether a product is a “particular model” includes:

(1) The description of the features and uses of the products in question in written material such as instruction manuals, description brochures, marketing or promotional programs, reports of certification of products, specification sheets, and product drawings.

(2) The differences or similarities between products in their observable physical characteristics and in components or features that are not readily observable and that are incorporated in those products for safety-related purposes;

(3) The customs and practices of the trade of which the manufacturer is a

member in marketing, designating, or evaluating similar products.

(4) Information on how consumers use the products and on consumer need or demand for different products, such as products of different size. In analyzing whether products are different models, differences in size or calibration afford the basis for distinguishing between products only if those differences make the products distinctive in functional design or function.

(5) The history of the manufacturer’s model identification and marketing of the products in question;

(6) Whether variations between products relate solely to appearance, ornamentation, color, or other cosmetic features; such variations are not ordinarily sufficient to differentiate between models.

(7) Whether component parts used in a product are interchangeable with or perform substantially the same function as comparable components in other units; if they are, the use of such components does not afford a basis for distinguishing between models.

(8) Retail price. Substantial variations in price arising directly from the characteristics enumerated in section 37(e)(2) for evaluating product models may be evidence that products are different models because their differences are distinctive. Price variations imposed to accommodate different markets or vendors are not sufficient to draw such a distinction.

(9) Manufacturer’s designation, model number, or private label designation. These factors are not controlling in identifying “particular models”.

(10) Expert evaluation of the characteristics of the products in question, and surveys of consumer users or a manufacturer’s retail customers.

(b) The definition of “consumer product” expressly applies to components of consumer products. Should a component manufacturer be joined in a civil action against a manufacturer of a consumer product, the section 37 reporting requirements may apply to that manufacturer after a combination of three judgments or settlements involving the same component model during a two year period, even though the manufacturer of the finished product is exempt